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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,783	12/21/2000	Kenneth Jacobs	GIN-6054CP	1408

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EXAMINER
MITRA, RITA

ART UNIT	PAPER NUMBER
1653	14

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/746,783	JACOBS ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

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DETAILED ACTION

Status of the Claims

Applicants' amendment and response to the office action dated July 2, 2002, filed on December 6, 2002 (paper #11) is acknowledged. Claims 31, 69, 109, 121, 166, 198, 239 and 260 have been canceled. Claim 30 has been amended and entered. Therefore, claim 30 is currently pending and is under examination.

Response to Remarks and Arguments

Applicants urge that (page 3) regarding non-elected claims directed to polynucleotides (claims 68, 108, 114, 165, 192, 238 and 253), it was understood the Rules of Practice permitted Applicants to simultaneously prosecute up to ten unrelated sequences. In response to the request for a clarification it should be noted that the polynucleotide of claims 68, 108, 114, 165, 192, 238 and 253 are unrelated and differ with respect to their structures and physicochemical properties. The polynucleotides have separate and distinct sequences and encode unrelated proteins, therefore the inventions are distinct (see Election/Restriction, paper #8).

Withdrawal of Rejections.

The rejection of claim 30 under **35 U.S.C. 112, first paragraph** is withdrawn in view of an enclosure of the Deposit Declaration in compliance with the Budapest Treaty.

The rejection of claim 30 under **35 U.S.C. 112, second paragraph** is withdrawn in view of applicants' amendment of subparts (l) and (i) of claim 30.

Rejection under 35 USC § 101

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title"

Claim 30 remains rejected **under 35 U.S.C. 101** because the claimed polynucleotides are not supported by either a specific and substantial asserted utility or a well established utility

because the specification fails to assert any utility for the claimed polynucleotides or the encoded proteins.

In response, applicants traverse the foregoing rejection and assert (page 4, paper #11) that the claimed subject matter is a full-length clone that encodes a secreted protein isolated from human adult testes (Specification page 144, line 35) that is sufficiently similar to human adult T cell leukemia derived factor, especially ATL-derived factor/thioredoxin that those of ordinary skill expect it to share activity with these proteins and believe they will exhibit thioredoxin catalytic activity (Specification page 144, lines 14-29). Applicants' statement has been noted and their attention should be drawn to the office action dated July 2, 2002, where it was stated that the specification, on pages 14-16 and 144-145 describes clone fq505_4 to which the instant invention relates. Applicants assert (page 145) that based on various alignments with database submissions; the claimed polynucleotides may encode polypeptides that share some activity with (Recombinant human adult T cell leukemia derived factor polypeptide), X54539 (thioredoxin), X77584 (ATL-derived factor/thioredoxin), GenProt135773 (surface associated sulphydryl protein) for example. The alignments have not been provided and no percent similarity is disclosed. The specification fails to provide any activity of the polynucleotide sequence of the clone fq505_4 or any activity of the protein encoded by the claimed polynucleotide, which would be similar as to the activity of an ATL-derived factor protein or a thioredoxin protein or a sulphydryl protein. A sequence comparison search for SEQ ID NO: 18 and SEQ ID NO: 19 using FastDB sequence database indicates the alignments and percent similarity to sequences cited by the applicants and indicated having similar activity (specification page 145), identified as Accession NOs: X77584 teach a nucleic acid sequence having 38% sequence identity to SEQ ID NO: 18 (see comparison result, FastDB, IntelliGenetics database), and X54539 teach a nucleic acid sequence having 31% sequence identity to SEQ ID NO: 18 (see comparison result, FastDB, IntelliGenetics database).

A sequence identity search for SEQ ID NO: 18 and SEQ ID NO: 19 using nucleic acids and protein sequence databases indicates a secreted protein having 100% nucleic acid sequence identity to SEQ ID NO: 18, (see alignment result, Database: N_Geneseq_032802, Accession NO: AAV99731) and 100% amino acid sequence identity to SEQ ID NO: 19, (see alignment

result, Database: A_Geneseq_032802, Accession NO: AAW95351). Thus it indicates that the SEQ ID NO: 18 and SEQ ID NO: 19 has a higher sequence identity to secreted protein (discussed in 102 rejection, previous office action) compared to sequence identity to thioredoxin as in X54539 or ATL-derived factor protein as in X77584 (see specification page 145). Therefore, only on the basis of some similarity to sequences identified as thioredoxin or ATL-derived protein, the protein of clone fq505_4 cannot be identified as a member of 'thioredoxin' or "ATL-derived" protein family. Moreover, the specification fails to provide any activity of the polypeptide of SEQ ID NO: 19, which would be similar to the activity of a 'thioredoxin' or "ATL-derived" protein. Applicants' response fails to address this issue of the rejection raised in the previous office action.

In response, Applicants statement (paper #11 page 5) "The Examiners' point concerning the unpredictability of protein activity from known homologous sequences is not well taken by those of ordinary skill, see for e.g., "Principals of Protein Structure, Cantor, ed. (1978) 167 wherein it is explicitly taught that homologous protein result from speciation or differentiation... Speciation is the evolution of homologous proteins possessing a common function in different organisms" has been considered but not found persuasive. It should be noted that Cantor has stated that speciation is the evolution of homologous proteins possessing a common function in different organisms, while the claimed invention does not embrace species homologues (it is assumed from Applicants' interpretation of Cantor and correlating the claimed protein with a species homologue). To address species homologue it should be noted that in the specification there is no guidance about what percent identity the two encoding genes of species homologue must have, no specific probe/primer and specific hybridization of PCR conditions which can be used so that one would reasonably expect the DNA obtained under those specific conditions is a species homologue. The specification provides insufficient guidance to allow one skilled in the art to obtain species homologues because the method to do so presented on page 205, lines 21-23, recites only "Species homologues may be isolated and identified by making suitable probes or primers from the sequences provided herein and screening a suitable nucleic acid source from the desired species." There is no information about how to identify a "suitable" probe or primer. Additionally, species homologues often display low sequence identity so that identification based solely on sequence similarity is unpredictable. Under such common circumstances, if one cannot

test for an expected activity of the encoded putative species homologue, then it is impossible to confirm existence of species homologues. Neither sufficient structural guidelines to reliably identify species homologues nor a specific function, which could be used to confirm that an isolated nucleic acid was a species homologue of a recited polypeptide, is provided in the specification. Further, the term "homologue", if only sequence similarity is used to establish "homology," cannot define a connection of common evolutionary origin nor necessarily common biological activity. Nucleic acids, which encode proteins that are species homologue, would have a common evolutionary origin. Specification fails to describe or demonstrate such proteins that are species homologue having a common evolutionary origin and possessing a common function. This situation requires carrying out further research to identify or reasonably confirm a "real world" context of use and therefore do not define specific and substantial utility.

Applicants urge at page 6 (paper #11) that Example 10 in the training materials of 'The Revised Interim Utility Guidelines' acknowledges that homology between the known and unknown protein is sufficient to ascribe the known protein's function to the unknown; thus the claim possesses credible, substantial and specific utility. Applicants' arguments have been fully considered but not found persuasive. The example 10 in the training materials of The Revised Interim Utility Guidelines describes a situation in which a cDNA encoding an ORF is claimed, where the cDNA is described in the specification as having "a high level of homology to a DNA ligase" and therefore training material indicates that the sequence encodes a DNA ligase, and that because DNA ligases have a well-established use, the claimed sequence has a well-established use. Applicants further assert that likewise, fq505_4 has sufficient homology to known proteins that exhibit thioredoxin, which have a specific and substantial utility. Applicants' arguments are fully considered but not found persuasive because specification fails to describe or demonstrate fq505_4's structural and functional similarity to thioredoxin proteins. Moreover, it is not clear if the sequence that is some percentage similar to thioredoxin protein encompassing the entire ORF encoded by the fq505_4 cDNA. Therefore, how it can be compared with the example 10, where the claim is a cDNA encoding an ORF, where the cDNA is highly homologous to a DNA ligase. Furthermore, DNA ligase is well known for its specificity and has a well-established utility. The thioredoxin proteins are more generic compared to DNA ligases, and situation described for DNA ligase in the example 10 is different from the situation of the

present invention, therefore, the utility of the present invention would not be established by mere comparing the two different situations.

In response to Applicants' citation of *In re Folkers* , where a new compound belonging to the known family of quinines and hydroquinones was alleged, without more, to have the electron transport activity of that known class. Furthermore, Applicants have stated that (page 7) the predecessor court to the Federal Circuit held that function is inferred based on similarity to a substance with a known function. However, Applicants should note that further it is stated in *In re Folkers* that " some uses can be immediately inferred from a recital of certain properties; question is not whether specific property is a use, but whether knowledge of that property necessarily and implicitly renders it readily apparent to one of ordinary skill that compound is useful." Therefore, *Folkers* is unpersuasive because in the instant case Applicants' assertion of utility is on the basis of structural similarity with ATL-derived factor, which has 38% sequence homology to SEQ ID NO: 18, and with thioredoxin which has 31% sequence homology to SEQ ID NO: 18 while protein of SEQ ID NO: 18 and SEQ ID NO: 19 has a higher sequence identity to secreted protein (discussed in 102 rejection, office action, paper #8)) compared to sequence identity to thioredoxin as in X54539 or ATL-derived factor protein as in X77584 (see specification page 145). Therefore, this reason is sufficient for one skilled in the art to question the statement of utility, how it would be readily apparent to one of ordinary skill that the compound is useful?

Rejection under 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30 remain rejected under **35 U.S.C. 112, first paragraph**. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Rejection under 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

Claim 30 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 30 is indefinite because it is not clear from the claim or the specification how in claim 30 (h), that the polynucleotide that must hybridize to the polynucleotide of items (a-g) of claim 30 encodes the same protein. In one instance, the polynucleotide is the coding strand and in the other it is the non-coding strand. If the coding strand contains 5' ATG (encodes Met), the non-coding strand is 5' CAT (encodes His).

Note that "ATCC" is a registered trademark. Please spell out in full as "American Type Culture Collection"and delete "ATCC" from the claim.

Rejection under 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 30 remains rejected under 35 USC 102 (a) as being anticipated by Agostino et al. (June 11, 1997). Agostino et al. (AAV99731) teach a cDNA clone fq505_4 codes for a human secreted protein (AAW95351) from human adult testis cDNA library, wherein the secreted protein nucleic acid sequences correspond to clone fq505_4 having 100% nucleic acid sequence identity to SEQ ID NO: 18, (see alignment result, Database: N_Geneseq_032802, Accession NO: AAV99731) and 100% amino acid sequence identity to SEQ ID NO: 19, (see alignment result, Database: A_Geneseq_032802, Accession NO: AAW95351). Agostino's cDNA insert length is 481 bp, that encodes a protein having 107 amino acids of SEQ ID NO: 19, therefore this sequence is considered for hybridizing to the polynucleotide of claim 30 that encodes a protein

of SEQ ID NO: 19. Agostino's clone fq505_4 is deposited in composite clone ATCC 98451, thus Agostino et al. anticipate claims 30 of the instant application. In response Applicants indicate (page 8, paper #11) that Agostino's protein may have 100% identity to SEQ ID NO: 19, but such is no longer relevant to subpart (e) (original), which has been deleted from claim 30. This argument is not persuasive because Agostino's protein is also relevant to amended subpart (d) and (e) the mature protein of coding sequence of clone fq505_4 deposited in ATCC 98451. The sequences of mature forms of the protein is present in the sequence of full length protein and also it is determinable Furthermore, Applicants indicate that fq505_4 is supported by 60/086236 filed June 11, 1997 and so Agostino is not a prior art. However, it should be noted that the provisional application 60/086236 has not provided any CRF and thus fails to provide the support to clone fq505_4 and SEQ ID NO: 18 and SEQ ID NO: 19. For this reason Application 09/092722 filed on June 5, 1998 was considered for the priority date applied in the present application. (see office action in paper #8).

Claim 30 remains rejected under 35 USC 102 (a) as being anticipated by Jacobs et al. (WO 98/56909, June 11, 1997). Jacobs et al. ('909) teach a polynucleotide as set forth in SEQ ID NO: 1 encoding human secreted protein as set forth in SEQ ID NO: 2 (claim 1 of '909). The cDNA clone fq505_4 of Jacob is deposited in composite clone ATCC 98451 (see summary and claim 1 and page 16, 29 and 32, of '909), thus anticipating claim 30 of instant application. Jacobs' polynucleotide sequence is considered for hybridizing to the polynucleotide of SEQ ID NO: 18 of claim 1 (a-i); and polypeptide sequence is considered for a protein of SEQ ID NO: 19; and thus anticipates claim 30 of instant application. As to Jacobs, Applicants comment that such claims priority to 09/092722, as does the instant application. In response Applicants should note that the priority date June 5, 1998 is applied to the present application hence Jacobs et al. is a prior art. (see supra and office action in paper#8).

Conclusion

No claims are allowable.

Applicant's amendment broadening the claim(s) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See

MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rita Mitra, Ph.D.
April 17, 2003

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